IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

ALKEM LABORATORIES LTD., AUROBINDO PHARMA USA INC., AUROBINDO PHARMA LTD., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, LAURUS LABS LIMITED, LAURUS GENERICS INC., MACLEADS PHARMACEUTICALS LTD., MACLEODS PHARMA USA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD.,

Defendants.

C.A. No. 21-1330-LPS

Original Version: December 6, 2021
Public Version: December 13, 2021

TORRENT'S OPPOSITION TO NOVARTIS'S MOTION TO DISMISS TORRENT'S COUNTERCLAIMS REGARDING THE '226, '143, '192, AND '667 PATENTS

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Dated: December 6, 2021

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I. INTRODUCTION

This motion is about late-listed Orange Book patents that Novartis refuses to bring into the on-going litigation over Torrent's ANDA for a generic version of Novartis's Entresto®. During the course of the original litigation, Novartis kept issuing and/or listing additional patents but denied Torrent's request to consolidate the newly issued/listed patents into the original litigation. Instead, Novartis brought the present suit against just one new patent (the unlisted '918 patent), forcing Torrent to file declaratory judgment counterclaims against the four "DJ patents," i.e., the newly listed '226 and '143 patents and the newly issued and listed '192 and '667 patents. Given that there is ongoing patent litigation on Torrent's ANDA, it is a waste of judicial resources to indulge Novartis's gamesmanship and delay resolution of other patent issues relating to that same subject. Therefore, Torrent opposes Novartis's motion to dismiss Torrent's counterclaims with respect to the DJ patents.

In its motion to dismiss, Novartis argues that (1) Torrent's counterclaims are barred by statute; (2) the Court should exercise its discretion and refuse to hear Torrent's claims; and (3) [redacted]. The Court should reject Novartis's arguments.

[redacted]

[1] [redacted]

[redacted]

Second, the Court should reject Novartis's attempt to transform its statutory-bar argument into a basis for the Court to exercise its discretion to deny declaratory judgment jurisdiction. The Hatch-Waxman Act facilitates early resolution of patent disputes. Torrent's counterclaims accomplish exactly that purpose. And, having obtained and/or listed the DJ patents after commencing litigation against Torrent on earlier listed patents, Novartis cannot complain that exercising jurisdiction would deprive Novartis of any notice or consideration period. Even before acquiring the DJ patents, Novartis was already on notice as to Torrent's ANDA and knew that the parties had an ongoing dispute with respect to patents purporting to cover Entresto® or Torrent's proposed ANDA product.

[redacted] But this is incorrect because 35 U.S.C. § 271(e)(2) deems submission of an ANDA a technical act of infringement, thereby creating jurisdiction, including declaratory judgment jurisdiction. [redacted] Novartis's amicus brief also recognizes that the purpose of the

Hatch-Waxman Act is to resolve such patent uncertainty before potential launch. [redacted] As a result, unless and until *GSK* is limited or overturned, those patents will hang over Torrent, threatening Torrent with a potential injunction and monetary damages should Torrent launch. Novartis's *GSK* arguments and actions here confirm there is a controversy of sufficient immediacy and reality to warrant declaratory judgment, and the purpose of the Hatch-Waxman Act dictates resolution now.

II. FACTUAL BACKGROUND

Novartis and Torrent are parties to the ongoing *In re Entresto (Sacubitril/Valsartan) Patent Litigation* action, MDL No. 20-2930, 19-1979-LPS (D. Del.), involving the '659, '331, '938, and '134 patents. Those patents issued between the years of 2012 and 2016, and were listed in the Orange Book in 2015 and 2016. The DJ patents were listed in the Orange Book two years later, in 2021. On September 1, 2019, Torrent notified Novartis of Torrent's recently submitted ANDA, including Torrent's paragraph IV certifications with respect to those patents. (D.I. 1 ¶ 73.) On October 17, 2019, Novartis sued Torrent for infringement of those patents, and Torrent counterclaimed for noninfringement and invalidity, although the '938 and '134 patents have since been dismissed as to Torrent per the parties' stipulation. (19-1979, D.I. 1 (complaint), 50 (answer and counterclaims), 340 (stipulation of dismissal, so ordered on Nov. 22, 2021).)

Although the '226 and '143 DJ patents had issued before Novartis brought its first suit against Torrent, Novartis had not yet listed those in the Orange Book. (Orange Book listing for Entresto®, Ex. A; D.I. 24, Exs. 1-2 ('226 and '143 patents).) The '667 and '192 DJ patents had not yet issued. (D.I. 24, Exs. 3-4 ('667 and '192 patents). While the 19-1979 litigation was

pending, Novartis amended its NDA and, on March 16, 2021, submitted the two already-issued HF-PEF patents (the '226 and '143 patents) for listing in the Orange Book. (Ex. A.) Later in 2021, the '667, '918, and '192 patents issued, and Novartis submitted the '667 and '192 patents, but not the '918 patent, for Orange Book listing. (*Id.*) Thus, all four DJ patents were listed in the Orange Book after Torrent's ANDA was submitted and accepted, and Novartis had already sued Torrent over earlier listed patents. Novartis then filed the present 21-1330 suit against Torrent but asserted only the unlisted '918 patent and none of the late-listed DJ patents.

[redacted]

Torrent (with other defendants) proposed to Novartis to add the DJ patents and the '918 patent to the original 20-md-2930 litigation. (Ex. B.) Novartis rebuffed or ignored such proposals and, on September 20, 2021, brought the present suit against Torrent for infringement of the unlisted '918 patent only. (D.I. 1.) On October 4, Torrent accepted service of the '918 complaint, reiterating its desire to address all patents in the existing litigation. (Ex. C.) Novartis did not respond. (*See id.*) On October 22, Torrent answered Novartis's allegations relating to the '918 patent and counterclaimed as to the DJ patents. (D.I. 24.) Still refusing to resolve the parties'

[2] [redacted]

disputes surrounding the DJ patents, on November 12, Novartis moved to dismiss Torrent's counterclaims as to those patents. (D.I. 40.) [redacted] Novartis ignored Torrent's request.

III. ARGUMENT

A. Torrent's Declaratory Judgment Counterclaims Regarding the '226, '143, '192, and '667 Patents Are Not Barred by Statute

Novartis's motion presents an issue of statutory construction Torrent believes to be one of first impression. Novartis relies on 21 U.S.C. § 355(j)(5)(C)(i)(I). That statute provides a 45-day waiting period, but, through incorporation of 21 U.S.C. § 355(j)(5)(B)(iii), it does so only for patents that (1) have been submitted for listing in the Orange Book ***before*** the date on which the ANDA (excluding amendments/supplements), later determined by the FDA to be substantially complete, was submitted; and (2) against which paragraph IV certifications have been filed. But Novartis has listed all of the DJ patents ***after*** Torrent's ANDA was filed, [redacted]

1. 35 U.S.C. § 271(e)(2) Establishes Declaratory Judgment Jurisdiction

Novartis focuses on 21 U.S.C. § 355(j)(5)(C)(i)(I). However, before explaining the inapplicability of that provision, which contains a limitation on otherwise existing declaratory judgment jurisdiction, Torrent first will explain how 35 U.S.C. § 271(e)(2) provides an affirmative basis for Torrent's counterclaims. Section 271(e)(2) of the Patent Act provides that "[i]t shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act," i.e., an ANDA, "for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2). The Federal Circuit has held that submission of an ANDA alone, not submission of a paragraph IV certification, creates justiciable controversy.

Vanda Pharms. Inc. v. West-Ward Pharms. Int'l, Ltd., 887 F.3d 1117, 1124-25 (Fed. Cir. 2018) ("Here, [brand plaintiff's] complaint alleged that [generic defendant] infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA. Nothing more was required to establish the district court's subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a). … The mere fact that [defendant] had not submitted a Paragraph IV certification for the '610 patent until after Vanda filed suit does not establish that there was not a justiciable controversy over which the court could exercise jurisdiction." (internal citation omitted)); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007) ("Under 35 U.S.C. § 271(e)(2)(A), submitting an ANDA, regardless of how many paragraph IV certifications it may contain, it is a single act of infringement[] ….").

Novartis does not dispute that Torrent filed an ANDA seeking approval for a generic version of Entresto® prior to expiration of the DJ patents and that Novartis, through addition of the DJ patents to the previously listed patents for Entresto in the Orange-Book, believes they cover the same subject matter. As the Federal Circuit explained in *Teva*: "There is no question that under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA." *Teva*, 482 F.3d at 1342. And, as the Federal Circuit further explained, jurisdiction is a two-way street:

> There is no question that under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA; indeed, that is exactly what occurred in this case. It logically follows that if such an action creates a justiciable controversy for one party, ***the same action should create a justiciable controversy for the opposing party***. In fact, the Supreme Court has stated: "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit inquiry are reversed; the inquiry is the same in either case."

Id. (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added).

Thus, 35 U.S.C. § 271(e)(2)(A) creates jurisdiction for an ANDA filer's declaratory judgment action. This is independent from Novartis's cited statutes, i.e., 21 U.S.C. § 355(j)(5)(C)(i)(I) and 35 U.S.C. § 271(e)(5), which the Federal Circuit in *Teva* addressed. *See id.*

2. 21 U.S.C. § 355(j)(5)(C)(i)(I) Imposes a 45-Day Waiting Period on Declaratory Judgment Suits Only for Orange-Book Patents That Were Listed Prior to Submission of the ANDA and Against Which the ANDA Applicant Has Provided Paragraph-IV Certification

While 35 U.S.C. § 271(e)(2) creates declaratory judgment jurisdiction for an ANDA filer, 21 U.S.C. § 355(j)(5)(C)(i)(I) puts certain limitations on exercise of this declaratory judgment jurisdiction. 21 U.S.C. § 355(j)(5)(C)(i)(I) provides:

> (I) … No action may be brought under by an applicant under paragraph (2) for a declaratory judgment ***with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii)*** unless—
>
> > (aa) the 45-day period referred to in ***such subparagraph*** has expired;
> >
> > (bb) neither the owner of ***such patent*** nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by ***the patent*** brought a civil action against the applicant for infringement of ***the patent*** before the expiration of such period[] ….

21 U.S.C. § 355(j)(5)(C)(i)(I) (emphasis added). Thus, for "a patent which is the subject of the certification referred to in subparagraph (B)(iii)"—and only such a patent—an ANDA filer must wait for the expiration of the 45-day period referred to in subparagraph (B)(iii) before filing a declaratory judgment action.

Subparagraph (B)(iii), in turn, defines a certain, narrowly defined class of patents:

> (iii) ***If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii)***, the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement ***of the patent that is***

> ***the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted***. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, ….

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). To be "a patent which is subject to the certification referred to in subparagraph (B)(iii)," a patent must meet at least the following two requirements: (1) the ANDA filer must have submitted a paragraph IV certification against such patent; and (2) the NDA holder must have submitted the patent for listing in the Orange Book ***before*** the date on which the ANDA (excluding amendments/supplements), later determined by the FDA to be substantially complete, was submitted. The second requirement was added by 2003 statutory amendments, which eliminated the possibility of multiple thirty-month stays for the same ANDA by ensuring that only patents submitted for listing in the Orange Book prior to ANDA filing qualify for the stay. *Vanda*, 887 F.3d at 1128.

The requirements for a patent to fall within the purview of subsection (B)(iii) and, therefore, subsection (C)(i)(I) have a common origin: they are the same requirements in determining whether an NDA filer is entitled to a 30-month stay. To that end, any argument that subsection (C)(i)(I)'s reference to subsection (B)(iii) encompasses the paragraph IV certification aspect of subsection (B)(iii), but not the remaining conditions, is wrong. From the plain reading of the text, if subsection (C)(i)(I) were to encompass only the paragraph IV certification, it could have directly referred to "subclause (IV) of paragraph (2)(A)(vii)," as does subsection (B)(iii). Because subsection (C)(i)(I) instead refers to (B)(iii), it must encompass all of the requirements subsection (B)(iii) imposes on a patent.

When amending the statue in 2003, Congress recognized the reality that, after an NDA holder commences Hatch-Waxman litigation against an ANDA filer, the NDA holder often obtains and lists in the Orange Book additional patents covering the same subject matter, and those patents should not be treated the same as patents listed prior to the ANDA filing. *See Vanda*, 887 F.3d at 1128. Congress thus amended 21 U.S.C. § 355(j) to eliminate the possibility of multiple thirty-month stays for the same ANDA. *Id.* The role of post-amendment subsection (B)(iii) is to provide a thirty-month stay of litigation for timely listed patents (i.e., listed before FDA acceptance of the ANDA) if the NDA/patent holder sues within 45 days of a paragraph IV certification on such a patent. Subsection (C)(i)(I), in turn, assures that the ANDA filer does not cut short the NDA/patent holder's 45-day period to determine whether to bring such a 30-month-stay-inducing suit. Because late-listed patents (i.e., listed after are FDA acceptance of the ANDA) are not entitled to a thirty-month stay regardless of when any suit is filed, the 45-day period is unnecessary, and subsection (C)(i)(I) is unnecessary.

Indeed, Novartis's actions in the present '918 patent litigation (21-1330) show that Novartis knows that a paragraph IV certification is not a prerequisite to declaratory judgment jurisdiction. In its complaint for infringement of the '918 patent, which Novartis has chosen not to list in the Orange Book, Novartis made sure to allege not merely infringement under 35 U.S.C. § 271(e)(2) (D.I. 1 ¶ 179) but also "declaratory judgment under 28 U.S.C. §§ 2201 and 2202" (*id.* ¶ 185). If Novartis can assert declaratory judgment claims based on the fact that Torrent has submitted its ANDA (and absent any paragraph IV certification for the '918 patent), so can Torrent. *See Teva*, 482 F.3d at 1342.

Novartis admits that 35 U.S.C. § 271(e)(5) of the Patent Act "works in conjunction with" 21 U.S.C. § 355(j)(5)(C)(i)(I) of the Hatch-Waxman Act. (Novartis Br. at 6.) On its face,

§ 271(e)(5) confirms the existence of, but does not limit, declaratory judgment jurisdiction. Thus, § 271(e)(5) does not alter the above analysis regarding the inapplicability of § 355(j)(5)(C)(i)(I) or provide any independent basis to limit declaratory judgment jurisdiction.

3. 21 U.S.C. § 355(j)(5)(C)(i)(I) Is Inapplicable to the DJ Patents

[redacted]

B. <u>The Court Should Exercise Discretion to Proceed With Torrent's Declaratory Judgment Counterclaims Regarding the '226, '143, '192, and '667 Patents</u>

1. Hatch-Waxman Is Designed to Resolve Patent Disputes Early

"To facilitate the approval of generic drugs as soon as patents allow, the Hatch–Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents." *Caraco Pharm. Labs. Ltd. v. Novo Nordisk AS*, 566 U.S. 399, 404 (2012). "The point is clarity. Hatch-Waxman is designed to resolve patent disputes as early as possible." *GSK*, 7 F.4th at 1345 (Prost, J. dissenting) (citing Brief of Amicus Curiae Novartis Pharms. Corp. and Sandoz Inc. in Support of Rehearing En Banc 7, 18-1976, ECF No. 168 (Fed. Cir. Dec. 30, 2020) (attached

as Ex. D)). Declaratory judgment suits by ANDA filers play an important role in preventing NDA holders from maintaining uncertainty by refusing to assert patents. Indeed, Congress enacted the "'civil action to obtain patent certainty' amendment to the Hatch Waxman Act" (21 U.S.C. § 355(j)(C)(5)) "to prevent patentees from 'gaming' the Hatch-Waxman Act" so as to avoid achieving patent certainty. *Teva*, 482 F.3d at 1342.

Novartis has used the tactic of selective assertions of its patents in infringement suits previously. In *Teva*, Novartis selectively sued Teva on only one paragraph IV patent, and then attempted to prevent Teva from pursuing a declaratory judgment action on the others. *Id.* at 1343. The Federal Circuit stated that: "[b]y filing a lawsuit on only one [of] its five patents certified under paragraph IV in Teva's ANDA, Novartis has tried to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibilities," i.e., to "reasonably cooperate in expediting the action." *Id.* It further explained: "Novartis' action insulates it from any judicial determination of the metes and bounds of the scope of the claims of its four Famvir® method patents in relation to design-around, a determination that is central to the proper function of our patent system and is a central purpose of the Hatch-Waxman Act." *Id.* The Federal Circuit proceeded to quote legislative history, explaining the importance of declaratory judgment actions in preventing brand's gaming the system by delaying resolution on selected patents:

> Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial patent suit.
>
> In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45–day period. We believe

> there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch–Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

Id. at 1344 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)). The limited applicability of the referenced "45-day period" was addressed in section III.A above.

2. Torrent's Declaratory Judgment Counterclaims Are Consistent With Legislative Intent of the Act and the Federal Circuit Precedent

In its appeal to the Court's discretion, Novartis gets it backwards. Novartis attributes "protections" to the cited statutes where they do not exist. As explained, the rule against declaratory judgment actions by an ANDA filer for 45-days following service of a paragraph IV notice is limited to patents that would lead to a 30-month stay. For late-listed patents, like the ones here, there is no need for the waiting period, and declaratory judgment jurisdiction is evaluated under 35 U.S.C. § 271(e)(2), which deems the filing of an ANDA a technical act of infringement and which confers jurisdiction on this act alone. Absent a potential 30-month stay, it does not matter whether the NDA holder or the ANDA filer brings suit, or when.

[redacted]

[redacted] Aside from the blatant unfairness resulting from the lack of the traditional two-way street for jurisdiction, *see Teva*, 482 F.3d at 1342, that would undermine a key purpose of the Hatch-Waxman Act—encouraging early resolution of patent disputes. [redacted]

Novartis cites *SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co., Inc.*, 552 F. Supp. 2d 500 (E.D. Pa. 2008), and *Paddock Laboratories, Inc. v. Ethypharm S.A.*, C.A. No. 09-3779, 2011 WL 149860 (D.N.J. Jan. 18, 2011), but they are easily distinguishable because they did not involve a late-listed patent, and both involved situations where a 30-month stay was potentially available. In *SB Pharmco*, the ANDA filer sent a paragraph IV notice before its ANDA had been accepted by the FDA, meaning that the ANDA was "in a kind of limbo" and was "not officially considered received or filed." 522 F. Supp. 2d at 506, 508. The *SB Pharmco* court was concerned that, if such a paragraph IV notice were considered valid, it would encourage generics to file "sham" or "substantially incomplete" ANDAs to "accelerate the timing provisions and litigation process," e.g., the 30-month stay. *Id.* at 508, 510 (quotation marks and citation omitted). In *Paddock*, after an initial ANDA filing and paragraph IV notice, the brand did not file suit within 45 days, and the ANDA filer filed a declaratory judgment suit. While that suit was pending, the FDA suspended review of the ANDA and took the drastic action of requiring the ANDA filer to reformulate its product, which the ANDA filer did, submitting a "Major Amendment" to its ANDA, adding an "outer capsule" to its product. 2011 WL 149860, at *3. The FDA then required

a new paragraph IV certification, which the ANDA filer submitted. *Id.* The brand then renewed a motion to dismiss the preexisting suit, arguing it was entitled to bring a new suit within 45 days after the new paragraph IV certification. *Id.* at *1. The court held that the statute did not prohibit maintenance of the ongoing suit but still declined to exercise jurisdiction in order to permit the brand an opportunity to file suit within the 45-day period from the new certification. *Id.* at *4. Because the patent at issue was timely listed, and the ANDA filer filed a paragraph IV certification, a 30-month stay was potentially available.

Novartis's other case for its discretion argument, *Amgen, Inc. v. Genentech, Inc.*, C.A. No. 17-7349, 2018 WL 910198 (C.D. Cal. Jan. 11, 2018), is inapposite because it involves a different statutory scheme, the Biologics Price Competition and Innovation Act (BPCIA), not the Hatch-Waxman Act. Also, there, the declaratory-judgment plaintiff skipped statutory procedures, violating the statute, before filing its suit. *Amgen*, 2018 WL 910198, at *3-4. As explained in section III.A above, the statutes raised by Novartis do not bar Torrent's counterclaims. As a further distinction, in *Amgen*, there was overlapping litigation in another district; not so here. *See id.* at *4. In addition, the *Amgen* parties had been negotiating under the BCPIA regarding which patents to litigate, creating an expectation that the patentee would soon, pursuant to the statute, bring suit, *id.*; here, [redacted]

Because Novartis's statutory argument fails, Novartis would not be denied any "protections" by having to defend against Torrent's counterclaims. Instead, the purpose of the Hatch-Waxman Act would be served by allowing Torrent's counterclaims.

C. [redacted] For the reasons explained in III.A.2 above, Novartis's statement that a "Paragraph IV certification is a statutory

prerequisite to an ANDA applicant's claim for declaratory judgment relief" is wrong. (Novartis Br. at 12.) Rather, it is Torrent's filing of its ANDA that provides Novartis an ability to sue for infringement under 35 U.S.C. § 271(e)(2). It also provides Torrent the right to sue for declaratory judgment. *See supra* § III.A.1. Moreover, Novartis fails to square its own declaratory judgment suit on the '918 patent, against which Torrent has not filed a paragraph IV certification, with its position that [redacted]

Because there is no statutory bar to Torrent's suit, the question is whether, as per traditional declaratory judgment principles, there is a substantial controversy between the parties of sufficient immediacy and reality to warrant issuance of a declaratory judgment. Numerous factors confirm there is. First, Novartis listed those patents in the Orange Book, thereby representing that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of a generic Entresto®. *See Teva*, 482 F.3d at 1341 (quoting 21 U.S.C. § 355(b)(1)). [redacted] *See id.* ("There is no question that under 35 U.S.C. § 271(e)(2), Novartis would have an immediate justiciable controversy against [Torrent] as soon as [Torrent] submitted the ANDA; indeed, that is exactly what occurred in this case. It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party."). Third, the statutory provisions cited by Novartis do not prohibit Torrent's suit and are designed to prevent the very "gaming" attempted by Novartis. *See id.* at 1342-44. Fourth, Novartis already sued Torrent on other Orange Book-listed patents and the unlisted '918 patent. *See id.* at 1344-45. Fifth, "the possibility that [Torrent] will be subject to multiple infringement suits from [Novartis]

based on the submission of a single ANDA … is an injury relevant to finding a justiciable controversy." *See id.* at 1345. [redacted] Sixth, Novartis has already sued a 20-md-2930 co-defendant in a separate suit for infringing the '226 and '143 patents, showing a willingness to assert those patents. 21-1347-LPS (D. Del.) (filed Sept. 24, 2021). Finally, [redacted] which obviously only added to the sufficient immediacy and reality to warrant declaratory judgment. (*See* Ex. C.) As the *Teva* court explained in the paragraph IV context, [redacted]

> We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

Teva, 482 F.3d at 1343 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)).

[redacted]

[redacted]

Regardless of the correctness of the *GSK* decision, at present, it is Federal Circuit law. Until there is clarification from the courts, [redacted] As the *GSK* dissent observes: [redacted] *accord id.* at 1359-60 (Prost, J., dissenting) ("The majority's opinion will create confusion for everyone. Under its analysis, the difference is indiscernible between this case and one in which the generic is safe."). Novartis made a similar observation in its amicus brief in support of rehearing, warning that "[t]he majority opinion creates uncertainty that will only worsen as courts struggle to reconcile it with longstanding precedent and apply it to different facts" and that "some patentees are already attempting to take advantage of and extend the ruling." (Ex. D at 8-9.) Despite this warning, the majority stuck to its guns on rehearing. [redacted]

[redacted]

Having its warning dismissed by the Federal Circuit, Novartis now becomes the opportunistic patentee it warned against. [redacted] would have its patents hang over Torrent, with Novartis lying in wait for Torrent to launch, so Novartis can then potentially seek an injunction and damages when it hurts most. This Court should heed Novartis's *GSK* warning and put a stop to Novartis's present gaming.

Novartis relies on various cases, only one of which, *AstraZeneca Pharmaceuticals LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012), [redacted] *AstraZeneca* is an example of the "longstanding precedent" that Novartis previously argued courts would "struggle to reconcile" with the Federal Circuit's original *GSK* decision, which was upheld on rehearing. (*See* Ex. D at 8.) [redacted]

IV. CONCLUSION

Torrent respectfully requests that Novartis's motion to dismiss be denied. Novartis's statutory argument ignores the statutory language. Novartis's request that this Court exercise its discretion to deny consideration of Torrent's counterclaims ignores the purpose of the Hatch-Waxman Act to achieve early resolution of patent disputes. [redacted]

Otherwise, Torrent is entitled to win freedom from the DJ patents through

litigation.

Dated: December 6, 2021

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